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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/693,643	10/20/2000	Pramod K. Srivastava	8449-073-999	8419

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PENNIE AND EDMONDS  
1155 AVENUE OF THE AMERICAS  
NEW YORK, NY 100362711

EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 12/02/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/693,643

Applicant(s)

SRIVASTAVA, PRAMOD K.

Examiner

Christopher H Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 4,9,13,17,21,25-42,44,46,47,82-91 and 93-106 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4,9,13,17,21,25-42,44,46,47,82-91 and 93-106 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/11/2003 has been entered.
2. Claims 1-3, 5-8, 10-12, 14-16, 18-20, 22-24, 43, 45, 48-81, and 92 are canceled without prejudice or disclaimer, claims 100-106 are newly added.
3. Claims 4,9,13,17,21,25-42, 44, 46-47, 82-91, and 93-106 are pending and examined on the merits.

### ***Information Disclosure Statement***

4. The Information Disclosure Statement filed 9/10/2003 (paper no. 2003) is acknowledged and considered. A signed copy of the IDS is attached hereto.

### ***Claim Rejection Maintained - 35 USC § 112, 1<sup>st</sup> paragraph***

5. The rejection of claims 4,9,13,17,21,25-42,44,46-47, 82-91,and 93-106 under 35 USC 112, 1<sup>st</sup> paragraph is maintained for the reasons of record. Applicant argues that the specification of the instant application allows the skilled artisan to practice the instant invention without undue experimentation. Applicant further argues that post

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filing evidence submitted as Feng and Feng II corroborates the invention as claimed for the prevention of cancer. Further, the applicant argues that the art at the time the invention was filed provided sufficient guidance in terms of screening or determining which members of a population were predisposed to developing cancer. Applicant's arguments have been carefully considered but are not found persuasive.

Reasonable guidance with respect to preventing any cancer relies on quantitative analysis from defined populations which have been successfully pre-screened and are predisposed to particular types of cancer. This type of data might be derived from widespread genetic analysis, cancer clusters, or family histories. The essential element towards the validation of a preventive therapeutic is the ability to test the drug on subjects monitored in advance of clinical cancer and *link* those results with subsequent histological confirmation of the presence or absence of disease. This irrefutable link between antecedent drug and subsequent knowledge of the prevention of the disease is the essence of a valid preventive agent. The instant specification provides a demonstration of the ability of HSP preparations (HSP70, HSP90, and gp96) to stimulate antigen presenting cells (i.e. dendritic cells). The specification has not taught to one of skill in the art at the time the invention was made how to prevent cancer using the combination of a "vaccine composition" in conjunction with an HSP preparation. Furthermore, the post filing references provided by the applicant are not sufficient to enable the skilled artisan to prevent cancer at the time of filing because it was not known at the time of filing that the combination of "vaccine composition" and HSP preparation would be effective in prevention. The state of the art existing at the filing

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date of the application is used to determine whether a particular disclosure is enabling as of the filing date. Publications dated after the filing date providing information publicly first disclosed after the filing date generally cannot be used to show what was known at the time of filing. In re Gunn, 537 F.2d 1123, 1128, 190 USPQ 402, 405-06 (CCPA 1976); In re Budnick, 537 F.2d 535, 538, 190 USPQ 422, 424 (CCPA 1976).

The Feng *et al* and Feng II were both published after the date of filing. As such, one of skill in the art would not be able determine based on the information taught in the art or from the state of the art at the time of filing that the invention would predictably function as claimed without having to undergo undue experimentation.

The treatment of cancer in general is at most unpredictable; as underscored by Gura (Science, v278, 1997, pp.1041-1042) who discusses the potential shortcomings of potential anti-cancer agents including extrapolating from in-vitro to in-vivo protocols, the problems of drug testing in knockout mice, and problems associated with clonogenic assays. Indeed, since formal screening began in 1955, thousands of drugs have shown activity in either cell or animal models, but only 39 that are used exclusively for chemotherapy, as opposed to supportive care, have won approval from the FDA (page 1041, 1<sup>st</sup> column) wherein the fundamental problem in drug discovery for cancer is that the model systems are not predictive. Given the fact that cancer treatment is at best unpredictable, any attempts to prevent it would also be consider unpredictable. All of this underscores the criticality of providing workable examples which is not disclosed in the specification, particularly in an unpredictable art, such as cancer therapy.

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In view of the teachings above, and the lack of guidance and or exemplification in the specification, it would not be predictable for one of skill in the art to practice a method of preventing cancer with a vaccine composition in conjunction with an HSP preparation as contemplated in the disclosure. Thus, it would require undue experimentation by one of skill in the art to practice the invention as claimed.

***Claim Rejections Maintained - 35 USC § 102***

6. The rejection of claims 4,9,13,27,30,33,42,44,46,82,86,90,93,94,95,97, 100 and 101 under 35 USC 102(b) as being anticipated by Chen *et al* is maintained for the reasons of record. Applicant argues that Chen *et al* does not teach each and every limitation of the instantly claimed invention because the method as taught by Chen *et al* only teaches the administration of a fusion of tumor associated antigen E7 to an HSP molecule and does not teach the administration of two distinct molecules. Applicant's arguments have been carefully considered but are not found persuasive. The claims as currently interpreted do not limit the administration of only two distinct molecules as argued by the applicant. Because the claims comprise open language and are entitled to the broadest interpretation possible, the fusion protein taught by Chen *et al* is encompassed within the scope of the instantly claimed invention. Chen *et al* teach a method of treating cancer with a protein that has two distinct portions, namely the E7 portion and the HSP70 portion both of which have or display different antigenicities. Applicant argues that two distinct substances are to be administered, however, the claims as interpreted do not preclude the two substances from being fused together.

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***Claim Rejections - 35 USC § 103***

7. The rejection of claims 4,9,33,42,46,82,86,90,94,95, 97, 100 and 101 under 35 USC 103(a) as being obvious over Chen *et al* is maintained for the reasons of record. Applicant's arguments are substantially the same as that made above for the 35 USC 102(b) rejection above. The claims as currently interpreted do not limit the administration of only two distinct molecules as argued by the applicant. Because the claims comprise open language and are entitled to the broadest interpretation possible, the fusion protein taught by Chen *et al* is encompassed within the scope of the instantly claimed invention. Chen *et al* teach a method of treating cancer with a protein that has two distinct portions, namely the E7 portion and the HSP70 portion both of which have or display different antigenicities. Applicant argues that two distinct substances are to be administered, however, the claims as interpreted do not preclude the two substances from being fused together.

**All other rejections are withdrawn in view of the applicant's amendments and arguments thereto as set forth in Paper No. 16.**

***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

*Christopher Yaen for:*

Christopher Yaen  
Art Unit 1642  
November 25, 2003